

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| | | | |
|--|--|--|------------------|
| Applicant's or agent's file reference MED-A0402P | FOR FURTHER ACTION | | See item 4 below |
| International application No. PCT/JP2004/012777 | International filing date (<i>day/month/year</i>) 27 August 2004 (27.08.2004) | Priority date (<i>day/month/year</i>) 29 August 2003 (29.08.2003) | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | |
| Applicant ANGES MG, INC. | | | |

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|---|--|---|--|
| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a). | | |
| 2. | This REPORT consists of a total of 6 sheets, including this cover sheet. | | |
| In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead. | | | |
| 3. | This report contains indications relating to the following items: | | |
| | <input checked="" type="checkbox"/> Box No. I | Basis of the report | |
| | <input type="checkbox"/> Box No. II | Priority | |
| | <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | |
| | <input type="checkbox"/> Box No. IV | Lack of unity of invention | |
| | <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | |
| | <input type="checkbox"/> Box No. VI | Certain documents cited | |
| | <input type="checkbox"/> Box No. VII | Certain defects in the international application | |
| | <input type="checkbox"/> Box No. VIII | Certain observations on the international application | |
| 4. | The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2). | | |

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|---|--|--|---|--------------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35 | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Date of issuance of this report 07 June 2006 (07.06.2006)</td> </tr> <tr> <td style="padding: 2px;">Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div></td> </tr> <tr> <td style="padding: 2px;">Telephone No. +41 22 338 70 10</td> </tr> </table> | Date of issuance of this report 07 June 2006 (07.06.2006) | Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div> | Telephone No. +41 22 338 70 10 |
| Date of issuance of this report 07 June 2006 (07.06.2006) | | | | |
| Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div> | | | | |
| Telephone No. +41 22 338 70 10 | | | | |

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

MED-A0402P

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/012777

International filing date (day/month/year)

27.08.2004

Priority date (day/month/year)

29.08.2003

International Patent Classification (IPC) or both national classification and IPC

**A61K48/00, 38/16, 31/7088, 9/08,
A61P1/00, 17/02, 17/06**

Applicant

ANGES MG, INC.

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

CORRECTED
VERSION

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/IP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/012777

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☒ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/012777

Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-15

because:

☒ the said international application, or the said claims Nos. 1-15
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of claims 1 to 15 relates to a
method of treatment of the human body by therapy or
surgery.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-15

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative
Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the
technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/012777

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|---|--|-------|-----|
| Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | |
| 1. Statement | | | |
| Novelty (N) | Claims | 16-45 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 16-45 | NO |
| Industrial applicability (IA) | Claims | 16-45 | YES |
| | Claims | | NO |
| 2. Citations and explanations: | | | |
| Documents: | | | |
| Document 1: WO 2002/089854 A1 (Anges MG Inc.), 14 November 2002 | | | |
| Document 2: WO 2002/000258 A1 (Medgene Bioscience, Inc.), 3 January 2002 | | | |
| Document 3: WO 2002/066070 A1 (Anges MG Inc.), 29 September 2002 | | | |
| Document 4: JP 2001-500858 A (Powderject Research Limited), 23 January 2001 | | | |
| Document 5: WO 99/31262 A2 (Genemedicine, Inc.), 24 June 1999 | | | |
| Document 6: JP 2002-542264 A (Powderject Vaccines, Inc.), 10 December 2002 | | | |
| Explanation | | | |
| <u>Claims 16 to 45</u> | | | |
| <p>The invention set forth in claims 16 to 45 is not disclosed in any of the documents cited in the international search report, and does not involve an inventive step in the light of documents 1 to 6 cited in the international search report.</p> <p>Document 1 sets forth a skin disease treatment or preventive agent for wounds or skin diseases and having</p> | | | |

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/012777

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

as its active ingredient an angiogenic factor gene such as hepatocyte growth factor (HGF); and that said agent is preferably administered non-orally to the portion affected by the skin disease of the periphery thereof. Document 1 also sets forth an example wherein HGF genes are subcutaneously injected to the edge of a wound, and document 2 indicates that genes such as prostacyclin synthesizing enzyme genes may be used alongside HGF as angiogenic genes. In addition, document 3 indicates that it is preferable that when applying to skin diseases agents for the treatment of skin diseases such as psoriasis vulgaris or ulcers and having as their main ingredient NK- κ B decoy oligonucleotides, said agent be administered locally to the area of the skin disease. Document 3 also sets forth an example wherein an ointment containing NF- κ B decoy is locally administered to the area affected by a skin disease.

In addition, in the field of gene therapy, a method employing a needle-free syringe and using air pressure or the like is known as a method of administering genes to skin and the surrounding tissue, as disclosed in documents 4 to 6, therefore it would be easy for a person skilled in the art to conceive of employing a method which uses different types of needle-free syringes as a method of administering a gene formulation such as NF- κ B decoy, prostacyclin synthesizing enzyme gene or HGF gene disclosed in documents 1 to 3.